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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/808,964

03/25/2004

Xiang-Jin Meng

AM100878-P1

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*7590

08/02/2006

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EXAMINER

CHEN, STACY BROWN

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/808,964

Applicant(s)

MENG ET AL.

Examiner

Stacy B. Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15, 16, 18-28 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 and 32-38 is/are ~~allowed~~ allowable. *SBC 7/28/06*
- 6) ☒ Claim(s) 4-10, 15, 16 and 18-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/4/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed May 16, 2006 is acknowledged and entered. Claims 1-10, 15, 16, 18-28 and 32-38 are pending. Claims 23-28 remain withdrawn from consideration, being drawn to non-elected subject matter. Claims 1-10, 15, 16, 18-22 and 32-38 are under examination.

The supplemental oath or declaration filed May 16, 2006 is acknowledged and accepted.

Response to Amendment

The rejection of claims 4-10, 15, 16 and 18-22 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is moot with respect to cancelled claims, and withdrawn with respect to pending claims in view of Applicant's amendments that clarify the claimed subject matter.

Claim Rejections - 35 USC § 112

Claims 4-10, 15, 16 and 18-22 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. One embodiment of the claims is drawn to a chimeric nucleic acid molecule (PCV1-2 construct) having at least 95% homology to the nucleotide sequence of SEQ ID NO: 2.

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This embodiment encompasses a large genus for which Applicant has not adequately demonstrated possession.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity (95%). There is not even identification of any particular portion of the structure that must be conserved. The specification does not provide examples of homologous nucleic acid molecules that are suitable for the invention. Without this knowledge, one of skill in the art would not be put in possession of the full scope of the claimed invention. SEQ ID NO: 2 has 1773 nucleotides. If one were to substitute, delete or add any nucleotides along the 1773 nucleotide sequence, the possibilities would be enormous. Applicant's disclosure fails to account for the large genus of polynucleotide molecules encompassed by the claim language, 95% homology. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Applicant's arguments have been carefully considered but fail to persuade. Applicant's substantive arguments are primarily directed to the following:

Applicant argues that the specification describes that the invention includes the use of nucleotide sequences having at least 95% homology to the chimeric nucleotide sequence (page 18, lines 1-18). Applicant asserts that 95% homology is a high percentage, and also a modest

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limit of nucleotide identity consistent with the broader teachings in the art, i.e., nucleotide sequences of PCV2 isolates may vary from around 80% to 99% of nucleotide sequence homology. For example, Fenaux *et al.* (*J. Clin. Microbiol.*, 2000, 38:2494-2503); Hamel *et al.*, (*J. Virol.*, 1998, 72:5262-5267); US Patent 6,703,023; and US Patent 6,287,856.

In response to Applicant's arguments, the Office recognizes that the degree of homology claimed, 95% at the nucleotide level, is relatively high in the art. The Office also recognizes that there is natural sequence divergence between various PCV2 isolates. However, the analysis for possession of nucleotides having 95% sequence homology to SEQ ID NO: 2, leaves Applicant's disclosure lacking. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factor present in the claim is a partial structure in the form of a recitation of percent identity (95%). There is not even identification of any particular portion of the structure that must be conserved. If one of skill in the art were to practice the claimed process with any variant within 95% homology of SEQ ID NO: 2, one would produce inoperative embodiments (since the variants have no specific function), and one would not even know where to begin the process of mutating the 95% homologous variants. Without a core structure and associated specific function, Applicant has not adequately provided a description of the claimed invention. While not all of the possible variants need be constructed, Applicant must provide a representative number of species of the genus claimed. Without this knowledge, one of skill in the art would not be put in possession of the full scope of the claimed invention. SEQ ID NO: 2 has 1773 nucleotides. If one were to substitute, delete or add any nucleotides along the 1773 nucleotide

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sequence, the possibilities would be enormous. Applicant's disclosure fails to account for the large genus of polynucleotide molecules encompassed by the claim language, 95% homology.

Further, the Office recognizes that claims have been issued in other patents that claim 90% homology, which is less than Applicant's claims to 95% homology. However, the patents that were cited, as well any other patent, are not binding to this particular application. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus. Therefore, the rejection is maintained for reasons of record.

Conclusion

Claims 4-10, 15, 16 and 18-22 remain rejected. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 7/28/06
STACY B. CHEN
PRIMARY EXAMINER